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Premarket Notification for the
WALLSTENT® Tracheobronchial
Endoprosthesis

16. 510(k) SUMMARY

General Information

<u>Date Prepared</u>	March 29, 1996
<u>Classification</u>	Class III
<u>Trade Name</u>	WALLSTENT® Tracheobronchial Endoprosthesis
<u>Common Name</u>	Tracheal Endoprosthesis
<u>Submitter</u>	Schneider (USA) Inc 5905 Nathan Lane Minneapolis, MN 55442 (612) 550-5848
<u>Contact</u>	Cathy Yohnk Senior Regulatory Affairs Associate
<u>Predicate Device</u>	WALLSTENT® Tracheobronchial Prosthesis, K934116 WALLSTENT® Tracheobronchial Prosthesis, K945494

Device Description

The WALLSTENT® Tracheobronchial Endoprosthesis is a self-expanding prosthesis constructed of biomedical superalloy and an elastomeric polymer. Smaller diameter models may utilize a radiopaque core. The prosthesis is a braided wire structure which may be covered with an elastomeric polymer in selected models. The outward radial force along with the ends of the device serve to stabilize the prosthesis after implanted. The prosthesis is offered in covered and uncovered version to allow physicians to select the most appropriate model based on their preference and individual patient

condition. The stent's purpose is to increase or maintain the inner luminal diameter of the tracheobronchial passage.

The stent is placed by means of a delivery system. The delivery system is a coaxial tubing assembly which constrains the prosthesis until it is released in a controlled manner. The release of the stent is accomplished by retracting the outer sheath. The prosthesis is packaged constrained on the delivery system ready for placement. The system is sterile and intended for single use only.

Indication

The WALLSTENT® Tracheobronchial Endoprosthesis is intended for use in the treatment of tracheobronchial strictures produced by malignant neoplasms or in benign strictures after all alternative therapies have been exhausted.

Technological Characteristics

This premarket notification deals with modification to the 12 and 14 mm diameter stents to standardize the relative radial force. This is accomplished by increased wire diameter and/or number of wires used to fabricate the stent

Summary

In summary Schneider (USA) Inc believes the above listed predicate devices and the WALLSTENT® Tracheobronchial Endoprosthesis are substantially equivalent based on design, materials, methods of fabrication and indications for use.